

## REMARKS

This Response is submitted in reply to the Non-Final Office Action mailed on February 22, 2008. A petition for a two month extension of time is submitted herewith. The Director is authorized to charge the amount of \$460.00 for the cost of the petition for a two month extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-696 on the account statement.

Claims 1-5 and 7-9 are pending. Claim 6 was previously canceled. In the Office Action, Claims 1-5 and 7-9 are rejected under 35 U.S.C. §103. For at least the reasons set forth below, Applicants respectfully submit that the rejections are improper and should be withdrawn.

In the Office Action, Claims 1-5 and 7-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,207,638 to Portman ("*Portman*") in view of U.S. Patent No. 6,620,778 to Mallee et al. ("*Mallee*") and U.S. Pat. No. 6,875,459 to Kopf et al. ("*Kopf*"). In contrast, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claim 1 recites, in part, a composition comprising a protein source consisting essentially of intact whey proteins in an amount ranging from 21 to 40% by total dry weight of the composition. Independent Claim 5 recites, in part a composition containing a protein source consisting essentially of intact whey proteins, wherein the intact whey proteins are administered in an amount of 0.1 to 0.8 g intact whey proteins per kg body weight during, before or after a standard meal. Applicants respectfully submit that there exists no motivation to combine the cited references and that, even if combinable, the cited references fail to disclose each and every element of the present claims.

In accordance with embodiments of the present invention, Applicants have surprisingly found that intact whey proteins significantly increase the production and/or secretion of insulin. For instance, administering to a person an effective amount of intact whey proteins enhances post-prandial insulinemia and/or decreases blood glucose levels. See, specification, page 5, lines 1-12. Further, Applicants have found that intact whey proteins induce a dramatic but short increase in plasma amino acids as opposed to proteins such as casein that are more slowly digested and which induce a mild but prolonged plateau of hyperaminoacidemia. See,

specification, page 4, lines 21-23. Applicants have also found through experimentation with diabetic patients, wherein the patients consumed treatments containing whey protein and treatments containing casein, that the AUC and  $C_{\max}$  kinetic parameters for the casein treatments were significantly lower than the treatments with whey protein. See, specification, Example 1.

Moreover, in view of Applicants findings with respect to the use of whey protein instead of casein, Applicants note that the present claims use the transitional phrase of “consisting essentially of.” As described in the previous response, the transitional phrase “consisting essentially of” limits the scope of a claim to the specific materials or steps and those that do not materially affect the basic or novel characteristics of the claimed invention. See, MPEP 2111.02; *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976). The Federal Circuit has also characterized a “consisting essentially of” claim as occupying a middle ground between closed claims of “consisting of” format and fully open claims of “comprising” format. See, *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Therefore, with regard to the present claims, the “consisting essentially of” language limits the protein source to intact whey proteins and those materials that do not materially affect the basic or novel characteristics of the claimed invention. Applicants respectfully submit that the casein disclosed in *Portman* materially affects the basic or novel characteristics of the claimed invention. As previously noted, Applicants distinguish casein from the intact whey proteins of the present invention by specifically noting that intact whey proteins induce a short, dramatic plasma amino acid increase compared to a prolonged plateau of hyperaminoacidemia induced by proteins such as casein. Moreover, Applicants specifically compare the effects of intact whey protein versus casein in the specification. The results establish that intact whey proteins have increased bioavailability and higher maximal plasma concentration of C-peptide than casein. See, specification, page 9, line 20 to page 14, line 9. Therefore, use of the lesser effective casein as a protein source in the present claims would materially affect the novel characteristics of the claimed invention by essentially canceling out the positive effects of intact whey proteins described in Applicants’ specification. Accordingly, the “consisting essentially of” language of the present claims is closed language that excludes casein as a possible material in Applicants’ invention. In contrast, the cited references fail to disclose each and every element

of the present claims and fail to even recognize the advantages of the presently claimed subject matter.

*Portman* fails to disclose or suggest multiple elements of the present claims. For example, *Portman* fails to disclose or suggest a composition containing a protein source consisting essentially of intact whey proteins as required, in part, by independent Claims 1 and 5. In fact, *Portman* actually teaches away from the use of intact whey proteins by teaching, for example, the use of casein, which Applicants have found to be more slowly digested and which induces a mild but prolonged plateau of hyperaminoacidemia. See, *Portman*, col. 5, lines 2-4. Moreover, *Portman* fails to disclose or suggest a protein source consisting essentially of intact whey proteins in an amount ranging from 21 to 40% by total dry weight of the composition as required, in part, by independent Claim 1. Further, *Portman* fails to disclose or suggest a protein source consisting essentially of intact whey proteins, wherein the intact whey proteins are administered in an amount of 0.1 to 0.8 g intact whey proteins per kg body weight as required, in part, by independent Claim 5. Instead, *Portman* is entirely directed toward nutritional intervention compositions that enhance and extend satiety in a calorically efficient manner. See, *Portman*, Abstract.

*Mallee* fails to disclose or suggest multiple elements of the present claims. For example, *Mallee* fails to disclose or suggest a composition containing a protein source consisting essentially of intact whey proteins as required, in part, by independent Claims 1 and 5. Moreover, *Mallee* fails to disclose or suggest a protein source consisting essentially of intact whey proteins in an amount ranging from 21 to 40% by total dry weight of the composition as required, in part, by independent Claim 1. Further, *Mallee* fails to disclose or suggest a protein source consisting essentially of intact whey proteins, wherein the intact whey proteins are administered in an amount of 0.1 to 0.8 g intact whey proteins per kg body weight as required, in part, by independent Claim 5.

In contrast, *Mallee* is entirely directed toward methods for preparing mixtures of peptides having cysteine and glycine contents. Contrary to the Patent Office's assertion that "*Mallee et al.* clearly teach that at 20% is a desirable amount by weight [of whey protein]," *Mallee*, in fact, does not disclose same. See, Office Action, page 4, lines 1-2. Instead, while *Mallee* teaches peptide mixtures having cysteine contents between 7-20 % by weight, *Mallee* fails to suggest at

any place in the disclosure a protein source consisting essentially of intact whey proteins in an amount ranging from 21 to 40% by total dry weight of the composition. In fact, not only does *Mallee* fails to disclose a protein source consisting essentially of intact whey proteins, but *Mallee* even discloses a composition containing calcium caseinate, which teaches away from the present claims. See, *Mallee*, Example 8. Calcium caseinate is a protein that is known to break down at a slower rate than whey protein. As such, *Mallee* even teaches away from the present claims.

*Kopf* fails to disclose or suggest multiple elements of the present claims. For example, while it is arguable whether *Kopf* even teaches the use of a composition containing a protein source consisting essentially of intact whey proteins, *Kopf* clearly fails to disclose or suggest the specific amounts claimed, namely (a) 21 to 40% by total dry weight of the composition (Claim 1) and (b) 0.1 to 0.8 grams intact whey proteins per kilogram body weight (Claim 5). In fact, *Kopf* does not appear to disclose a nutritional or pharmaceutical composition in the first place. Rather, *Kopf* seems to be directed to isolating proteins rather than using specific proteins in nutritional or pharmaceutical compositions.

For at least the reasons stated above, Applicants respectfully submit that the cited references fail to disclose each and every element of the present claims.

Applicants also respectfully submit that, even if combinable, there exists no reason why the skilled artisan would combine the cited references. For example, Applicants submit that each reference must be considered as a whole and those portions teaching against or away from each other and/or the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

In its attempt to arrive at the present claims by combining the cited references, the Patent Office has ignored significant portions of each reference that teach away from the combination. For example, *Portman* teaches away from the use of intact whey proteins by teaching, for example, the use of casein that, as Applicants stated above, is more slowly digested and induce a

mild but prolonged plateau of hyperaminoacidemia. See, *Portman*, col. 5, lines 2-4. In addition, *Portman* sets forth at col. 5, lines 2-4 and col. 6, lines 10-12, protein in the form of GMP is also included. Similarly, *Mallee* also teaches away from the present claims. As discussed above, *Mallee* discloses a composition containing calcium caseinate, which is a protein that is known to break down at a slower rate than whey protein in much the same way as caseins. See, *Mallee*, Example 8. Thus, *Portman* and *Mallee* not only fail to disclose or suggest the inventive feature of a protein source that includes only intact whey proteins, but also teach away from same.

Applicants respectfully submit that theses disclosure of *Portman* and *Mallee* would actually lead the skilled artisan in a direction divergent from the path that was taken by Applicants in the present disclosure. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001). See, also, MPEP 1504.03.

Further, the Patent Office has improperly applied hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. In fact, in the instant situation, the prior art provides no teaching or suggestion of the desirability of the modification. The fact that the prior art *may* be modified in the manner suggested by the Patent Office does not make the modification obvious. As a result, one having ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

Accordingly, Applicants respectfully request that the obviousness rejections of Claims 1-5 and 7-9 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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